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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/801,381
Filing Date: March 15, 2004
Appellant(s): FIGUEROA ET AL.

Walter W. Karnstein
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 4/10/2007 appealing from the Office action mailed 12/19/2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows:

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner: the examiner had previously rejected claims 1-3, 6-8, 29-30 and 32-33 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Voss et al (4322449).

The examiner is withdrawing the 102(b) portion of the rejection.

Thus, the rejection of claims 1-3, 6-8, 29-30 and 32-33 under 35 USC 102(b) as anticipated by Voss et al (4,322,449) is withdrawn.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,322,449	Voss et al	3-1982
5,894,841	Voges	4-1999

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

a) Claims 1-3, 6-10 and 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voss.

Voss teaches a method of applying a bioactive agent to a delivery substrate in the form of dots forming a desired geometrical pattern (See Abstract; col. 5, lines 35-37).

Voss teaches the control of various parameters, such as dots/second, volume/drop, concentration of the bioactive, number of ejection strokes, etc (1:60-65; 4:1-26; 6:1-7). As is known in the art and as taught in the specification, controlling the dot pattern, the size or shape of the dot, or the consistency of the size of the dots will inherently provide control over the dissolution rate. The precise nature of Voss' printing technique yields such control.

As for the limitation of first "identifying a target dissolution rate", Examiner notes that safe and effective administration of a drug (bioactive agent) to a patient requires a precise dose at an acceptable "target" dissolution rate. Medical professionals, such as doctors, pharmacists, and pharmaceutical company scientists, are of ordinary skill in this art. Medical personnel would have been aware that a too-rapid dissolution rate could lead to an over-dose, whereas a too-slow dissolution rate could lead to ineffective treatment levels. Neither of these risks is acceptable. Also, many medications are provided in a controlled release (CR) form to provide the correct dose over a period of time, inherently requiring the use of a target dissolution rate. Therefore, when creating a drug delivery substrate, it is Examiner's position that it would have been

inherent for one of ordinary skill in the art to identify, in addition to a desired target dose, a target dissolution rate. The patterns of dots placed down on the delivery substrate of Voss would have been inherently placed to achieve said target dissolution rate for the safety and health of medical patients.

One of ordinary skill in the art would have been well aware of the effects of surface area on dissolution rate, for example, that a plurality of small thin dots would dissolve faster than a thick, large dot. As evidence of this awareness, as outlined above, Voss teaches control of the parameters that would be known by ordinary artisans in the medical coating art to impact dissolution rate. Voss also recognizes the importance of dissolution rate in that the label on the carrier carries a "taking time" (see Example 2), i.e., a reminder to the patient that the effectiveness of the bioactive is about to wear off, and a new dose needs to be administered. This required knowledge of the dissolution rate of the bioactive, among other parameters.

Voss teaches the use of a piezoelectric ejection element (abstract) with a number of nozzles (4:18).

Voss refers to some dots as being discrete, with a specified volume (1:60-2:8). Dots are "spaced". Voss also uses his method to write letters (Ex. 2), requiring, in some instances, at least a partial overlap of dots.

Regarding claim 3, requiring sufficient spacing to avoid coalescing, Voss' method of creating spaced, discrete dots sufficiently spaces the dots.

Regarding claim 33, the substrate of Voss is ingestible (see Examples).

Voss fails to teach the standard deviation regarding the spacing or overlapping of droplets (claims 9-10). However, Voss goes to great lengths to discuss the precision, uniformity, and

reproducibility of the dot sizes, dosages, and concentrations he applies. Because a plate of nozzles may be used in a fixed arrangement, the dots formed should always be spaced the same, i.e., with a deviation approaching zero percent. It would have been obvious to an ordinary artisan wishing to achieve uniformity and precision in dosing to select and maintain a spacing that is consistent from dot to dot, i.e., with a standard deviation of less than 15%.

While achieving perfect uniformity is impossible, Voss' teachings clearly direct one of ordinary skill in the art to precisely space the dots with *no standard deviation*, i.e., with a deviation approaching 0%, which would be less than 15%. Voss creates dosage zones on his ingestible substrate with specific dosage ratios. Incorrect spacing would yield a zone with too many or too few dosage dots, leading to dosage error. Likewise, in creating letters, another embodiment of Voss, a uniform spacing of the dots which create the letters would be necessary to yield letters with smooth lines (letters made of dots with varying spacing would be thicker in some areas).

It is well settled that determination of optimum values of cause effective variables such as standard deviation is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Regarding claim 31, it is Examiner's position that in the creation of letters or other desired geometric patterns, Voss will desirably select a second dot to fully overlap a first dot to create a larger dot in a given location. It would have been within the skill of an ordinary artisan to "fully" overlap one dot with another if a larger "ink" spot is needed to create a letter, such as in, for example, dotting an "i".

b) Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voss, as applied above, in view of Voges (5,894,841).

Voss teaches that which is disclosed above, namely forming droplets of bioactive agent using piezoelectric ejection elements. What Voss does not teach is the use of thermal ejection elements.

It is Examiner's position that these two species of inkjet printing are obvious variants that would have been known to an ordinary artisan and cites Voges for teaching the same.

Voges teaches a method of forming droplets of bioactive agent by using one of the two forms of inkjet printing, namely either a piezoelectric ejection device or a thermal ejection device (3:62-66).

Since Voss teaches printing precise drops of bioactive agent using a piezoelectric element, such as is used in inkjet printing, and Voges teaches that either the piezoelectric or thermal types of inkjet printing are suitable for forming precise droplets of bioactive agent, Voges would have reasonably suggested the use of a thermal element in the method of Voss. It would have been obvious to one of ordinary skill in the art to use the interchangeability teachings of Voges in the method of Voss to provide Voss with a suitable, successful alternative element for dosing dots in a precise manner.

Like Voss, Voges teaches a plurality of nozzles or ejection orifices that provide uniformly-sized droplets.

(10) Response to Argument

a) Applicant argues that Voss does not identify a target dissolution rate.

An examiner may take into account the inferences and creative steps that a person of ordinary skill in the art would employ. Examiners may rely on their own technical expertise to describe the knowledge and skills of a person of ordinary skill in the art. Prior art is not limited just to the references being applied, but includes the understanding of one of ordinary skill in the art. The proper analysis is whether the claimed invention would have been obvious to one of ordinary skill in the art.

Voss teaches a method of applying a bioactive agent to a delivery substrate in the form of dots forming a desired geometrical pattern. A desired pattern of dots indicates a decision was made to select a specific pattern and location of all dots, the first, second, and subsequent ones. The precise dosing of the active substance, with precise control over volume, spacing and concentration will have the effect of controlling the dissolution rate of the active substance, and these parameters are therefore selected with this control in mind. The fact that "taking time" (Example 2) is applied to the carrier is an indication that dissolution rate is being accounted for in the application of the bioactive to the carrier, even if the term "dissolution rate" is not explicitly stated.

The safe and effective administration of drugs requires correct quantities (i.e., dose) at correct rates of administration (i.e., dissolution rates). Any pattern selected in the use of the Voss reference must be selected based on dose and rate. A delivery substrate pattern yielding the

incorrect dose and/or dose rate would be unacceptable. One of ordinary skill in the art must have these two factors in mind when creating a pattern of drug dots and when testing the delivery substrate. Even if the dose and dose rate are only tested in R&D after manufacture (but before sale), using a trial-and-error method, one of ordinary skill in the art must still have a desired target dose/dissolution rate in mind, i.e., one that was "identified". In fact, Applicant's own specification states that "a desired dissolution rate can be discovered through experimentation, in which one or more application parameters are varied until a desired dissolution rate is achieved" and that drop size, nozzle size, solution concentration, drying temperatures, and drop pattern are all appropriate parameters to vary (p. 20). These parameters would have all been well-known by one of ordinary skill in the medical coating and administering art to impact the rate at which a coating would dissolve from a substrate.

Further Voss teaches the control of these various parameters, such as dots/second, volume/drop, concentration of the bioactive, number of ejection strokes, etc. Examiner maintains that controlling the dot pattern, the size or shape of the dot, or the consistency of the size of the dots will inherently and/or obviously provide control over the dissolution rate. The precise nature of Voss' printing technique yields such control, which is imperative to safe dosing of bioactive agents. When dosing a patient, a physician inherently considers the amount of therapeutic agent in addition to the rate at which the dose is administered.

The applicant has further argued that Voss does not position dots at selected locations, such as overlapping drops, based on the target dissolution rate. The examiner would point to Voss's printing of dots in the form of letters (Example 2) as an example of controlling dot spacing, and inherently therefore dissolution rate.

b) The applicant has argued that Voges provides no suggestion as to how to modify the dissolution rate of the droplets of its droplet dispenser.

The examiner's position is that Voges teaches a conventional alternative to the piezo disperser of Voss, and is used for this teaching, not for a teaching of dissolution rate.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Erma Cameron

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